U.S. Patent Application No. 09/488,762 Amendment dated April 2, 2004 Reply to final Office Action dated December 2, 2003

REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

The amendment to the claims is editorial in nature and/or further defines what the applicants regard as their invention. Full support for the amendment can be found in the claims as originally filed, for instance, in claim 9, as well as throughout the specification. No new questions of patentability should arise since the Examiner has essentially considered similar subject matter in original claim 9. Further, no need for additional searching is necessitated for the same reasons. This amendment places the application in condition for allowance. At a minimum, the amendment places the application in a better condition for appeal. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

Claims 1-8 and 10 are pending in the application. Claim 9 has been canceled.

The applicants and the undersigned appreciate the telephone conversation with Examiner Mulcahy on February 25, 2004. In the telephone interview, the rejections set forth in the final Office Action and the differences between the claims of the present invention compared to the cited art relied upon by the Examiner were discussed. The Examiner indicated that the above amendments to claim 1 would assist in advancing the prosecution of this application. The substance of the telephone interview is set forth in the remarks below.

At page 2 of the Office Action, the Examiner rejects claims 1-10 under 35 U.S.C. §103(a) as being unpatentable over JP 02-001284, Haffner et al. (U.S. Patent No. 6,096,014), or Wehner et al. (U.S. Patent No. 6,063,981). The Examiner asserts that the reasons set forth under 35 U.S.C. §103 at pages 3 and 4 of the previous Office Action dated May 27, 2003 are deemed

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proper and are herein repeated. The Examiner then states that with respect to the Amendment dated September 26, 2003, in which the applicants argued that JP 02-001284 does not teach or suggest a stress relaxation ratio, and no evidence exists why such a property would be inherent from JP 02-001284. The Examiner believes that it would be reasonable to presume that the compositions mentioned in JP 02-001284 can possess properties which render the claimed invention obvious or anticipated. With respect to claim 5, the Examiner asserts that the claimed ratios can be found at page 6 of the English translation of JP 02-001284. Furthermore, with respect to the arguments set forth in the Amendment dated September 26, 2003 that Haffner et al. fails to discuss the stress relaxation properties of the tape, the Examiner again argues that Haffner et al. describes articles which are formed from the composition of the claimed invention. Therefore, the Examiner states that it would be reasonable to presume that the articles formed from the composition of the claimed invention would inherently possess properties which render the claimed invention obvious.

Furthermore, with respect to the arguments set forth in the Amendment dated September 26, 2003 that Wehner et al. differs from the claimed invention because the adhesive of Wehner et al. is intended for bonding substances together by surface attachment, the Examiner states that the claims of the present application describe a mental step (e.g., "is attachable"), which does not further limit the claimed invention. Furthermore, the Examiner states that one of ordinary skill in the art would readily appreciate that the adhesive of the cited art, which is intended to be attached to another surface, would certainly be attachable to skin. Accordingly, the Examiner maintains this rejection from the previous Office Action. For the following reasons, this rejection is respectfully traversed.

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Claim 1 recites, in part, a medical adhesive tape for adhering onto a skin surface. According to claim 1, the medical adhesive tape includes a supporting substrate and an adhesive layer directly or indirectly laminated thereon, wherein the supporting substrate includes a composition that includes 100 parts by weight of a thermoplastic resin, and 10 to 200 parts by weight of a silicic acid compound, wherein the medical adhesive tape is adherable to a skin surface, and wherein the supporting substrate has a stress relaxation ratio of 60% of less.

JP 02-001284 relates to an externally applicable aid which includes porous plastic substrates made of polyolefin resin, characterized by having 100-500 kg/cm of tensile strength, 50% or more of elongation, and 25-100 kg/cm² of 20% modulus. Furthermore, JP 02-001284 relates to an external application aid which is applied on an "injury" that requires aeration and moisture protection. In particular, JP 02-001284 relates to first aid medical sheets and large scale medical sheet dressings and draping materials, which are formed by coating pressure-sensitive adhesives over porous plastic substrates.

JP 02-001284 is distinct from the claimed invention. There is no teaching or suggestion of a stress relaxation ratio. Furthermore, no evidence exists why such a property would be inherent in JP 02-001284. This can be seen in the complete English translation of the reference. The material of JP 02-001284 includes a porous plastic substrate and a pressure-sensitive adhesive layer on one side. The substrate is required to be porous in order to provide sufficient permeability and aeration. Furthermore, even though JP 02-001284 uses fillers, JP 02-001284, at page 4, lines 16-22, states that the porous substrate is obtained by stretching, and thereafter eluting the soluble filler or organic material with acid or alkali solution. Thus, the filler described in JP 02-001284 need not be present in the final product. In fact, the filler may be removed by a

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solvent after forming a sheet.

Furthermore, with respect to the subject matter of claim 5 of the present application, which states that the amorphous or low crystalline polyolefin resin is present in an amount of 30 to 100% by weight, this is not taught or suggested in JP 02-001284 or the other cited references. As explained at page 15 of the present application, such an amount of this polymer blend provides the desired stress relaxation properties. Amounts below this level tend to show strong necking to decrease the preferred stress relaxation property. This benefit clearly is not taught or suggested in any of the cited references.

Haffner et al. relates to uniaxially-oriented microporous breathable films having exceptional toughness transverse to the direction of orientation. The material of Haffner et al. includes a copolymer of ethylene with at least one C₄-C₈ α-olefin monomer. According to Haffner et al., the breathable film is prepared by providing a polymeric resin and adding to the resin at least 40% by weight of a filler having a particle size that contributes to pore formation to form a filled resin. According to Haffner et al., such films have a variety of uses including diapers, training pants, sanitary napkins, incontinence devices, bandages, and the like. However, no discussion of stress relaxation properties of the tape in Haffner et al. is made. As illustrated in Example 8 of the present application, the claimed medical adhesive tape has a significant release relaxation property compared with those of comparative Example 8, which do not include a filler, or compared with comparative Example 9, which includes the calcium carbonate of Haffner et al.

Further, Wehner et al. relates to the use of an adhesive to prepare a disposable absorbent product, such that the disposable absorbent product exhibits desirable aesthetic properties. More

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specifically, Wehner et al. relates to an adhesive that is not visible through the outer sheets of the disposable absorbent product. According to Wehner et al., the adhesive is suited for use in disposable absorbent products, such as diapers, adult incontinent products, and bed pads; in catamenial devices, such as sanitary napkins, and tampons; and in outer absorbent products, such as wipes, bibs, wound dressings, and surgical capes or drapes, which are used to absorb a liquid, such as water, saline, synthetic urine, and body liquids, such as urine, menses, and blood. Furthermore, Wehner et al., at column 3, lines 24-27, specifically states that the term "adhesive" is intended to mean a substance that is capable of bonding other substances together by surface attachment. Wehner et al. simply does not teach or suggest that the adhesive is adherable to a skin surface. Further, Wehner et al. does not teach or suggest any stress relaxation properties.

With respect to the Examiner's argument that one of ordinary skill in the art would readily appreciate that an adhesive, which is intended to be attached to another surface, would certainly be attachable to skin, the Examiner's conclusion is simply incorrect. Not all adhesives are suitable for adhering to the skin.

Moreover, a combination of JP 02-001284, Haffner et al., and Wehner et al. does not teach or suggest a substrate composition that includes 100 parts by weight of a thermoplastic resin and 10-200 parts by weight of a silicic acid compound, and where the supporting substrate has a stress relaxation ratio of 60% or less. Thus, the Examiner's statement that it would be reasonable for one of ordinary skill in the art to presume that the references include the stress relaxation ratio of the claimed invention is unsupported and is based on hindsight. Furthermore, JP 02-001284 and Haffner et al. are not related to Wehner et al. The adhesive in Wehner et al. is specifically designed for bonding a substance to other substances, whereas the adhesive of

Haffner et al. and JP 02-001284 can be used in bandages and first aid medical sheets. Thus, one skilled in the art working with adhesives for bandages and first aid medical sheets would not look to Wehner et al. Accordingly, this rejection should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 1-8 under the 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Kobylivker et al. (U.S. Patent No. 6,002,064). The Examiner states that the rejections as set forth previously under 35 U.S.C. §102/103 are deemed proper and are herein repeated. In addition, with respect to the applicants' argument that the medical apparel identified by Kobylivker et al. does not suggest a medical adhesive tape which is applied directly to the skin, the Examiner states that the applicants' claim language is "for attaching" and "is attachable," which is broad enough to cover a gown which either ties or is hung over the shoulders or is even tied to a person or a skin surface. Furthermore, the Examiner states that such language does not limit the article to an adhesive tape which is adhered to the skin surface. For the following reasons, this rejection is respectfully traversed.

Claim 1 of the present application recites, in part, a medical adhesive <u>tape for adhering</u> onto a skin surface comprising a supporting substrate and an adhesive layer directly or indirectly laminated thereon, and wherein the medical adhesive tape is adherable to a skin surface.

It is important for the Examiner to appreciate that for such an adhesive to work properly in heath care applications, the adhesive must be pressure sensitive and capable of being removed without damaging the surface of a wound or other sensitive area. As anyone who has ever had a dressing removed from a wound can appreciate, the type of adhesive must be carefully chosen to provide enough adhesion to stick to the body, but that adhesive must also allow removal of the

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dressing without undue pain to the subject or damage to the skin.

Kobylivker et al., at column 2, lines 46-56 and column 9, lines 55-65, indicates that the film may be useful for the manufacture of gowns, gloves, and other types of medical apparel. However, Kobylivker et al. does not teach or suggest that it could be used as an adhesive tape for adhering onto a skin surface, wherein the medical adhesive tape is adhereable to a skin surface, which is a feature of the claimed invention.

Furthermore, Kobylivker et al., at column 8, describes <u>permanently bonding</u> the film to one or more substrates. This is quite different from the adhesive layer on the substrate of the claimed invention. Particularly, the present application, at pages 23 and 24, describes different classes of adhesives and, from the description, it is clear that the adhesives of the claimed invention are for purposes of <u>temporarily</u> adhering the medical adhesive tape to an object, such as the skin. Also, there is no teaching or suggestion of any stress relaxation property in Kobylivker et al.

In addition, claim 1 and the claims dependent thereon recite a medical adhesive tape. The language in the claim, at a minimum, is part of the preamble and provides meaning to the claims as further shown in the present specification. As set forth in M.P.E.P. §2111.02, which relates to the weight of a preamble, any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. Clearly, the term "medical adhesive tape" would not be encompassed by the type of clothing set forth in Kobylivker et al. The term "medical adhesive tape" as set forth in the claims cannot be ignored or rendered generic by the Examiner. Moreover, the claims of the present application specifically recite that the medical adhesive tape

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is adherable onto a skin surface. Therefore, Kobylivker et al. teaches away from the claimed invention. Accordingly, this rejection should be withdrawn.

At page 5 of the Office Action, the Examiner rejects claim 1 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicants regard as the invention. According to the Examiner, the expression "parts by weight of a thermoplastic resin and 10 to 200" is recited twice in claim 1 of the present application. For the following reasons, this rejection is respectfully traversed.

Claim 1 now recites that the supporting substrate comprises a composition which comprises 100 parts by weight of a thermoplastic resin and 10 to 200 parts by weight of a silicic acid compound. Accordingly, this rejection should be withdrawn.

At page 6 of the Office Action, the Examiner rejects claim 1 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicants regard as the invention. According to the Examiner, the expression "for attaching onto a skin surface" and "is attachable to a skin surface" is not supported by the specification. For the following reasons, this rejection is respectfully traversed.

The expressions "for attaching onto a skin surface" and "is attachable to a skin surface" are fully supported by the specification. To assist the Examiner, claim 1 now recites the expressions "a medical adhesive tape for adhering onto a skin surface" and "the medical adhesive tape is adherable to a skin surface." These expressions are also fully supported in the present application (for instance, at pages 2, 4, 21, 23, and 25). Accordingly, this rejection should be withdrawn.

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CONCLUSION

In view of the foregoing remarks, the applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

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